Summary of the Accrediting Authority Committee Teleconference December 18, 1996

The National Environmental Laboratory Accreditation Conference (NELAC) Accrediting Authority Committee met by teleconference from 1:00 to 3:00 p.m. Eastern Standard Time (EST) on Wednesday, December 18, 1996. The meeting was led by Committee Chair, Mr. John Anderson of the State of Illinois Environmental Protection Agency (IL-EPA). A list of action items is given in Attachment A. A list of Committee members/invited guests is given in Attachment B. A copy of the teleconference agenda is given in Attachment C.

INTRODUCTION

The purpose of the teleconference was to continue to discuss the updated version of Chapter 6. The following items were discussed:

- <u>Action Items Identified in the Minutes of the December 10, 1996, Teleconference</u> -- Minutes had been prepared and reviewed by Mr. Anderson but had not been approved by Ms. Jeanne Mourrain, NELAC Director, so they were not distributed to the Committee at this time. Each action item was identified as a revision in the current draft, so action items were discussed during the review of Revision 6, Chapter 6.
- Review of the Updated Version (Revision 6) of Chapter 6 -- The Committee reviewed revisions made to Chapter 6 as a result of discussions at the December 10, 1996, teleconference.
- Mr. Jim Meyer's Proposed Revision of Sections 6.7.1(d) and (e).
- "Unconditional" Reciprocity, Section 6.2(c).

Ms. Emily Williams, recording secretary, Research Triangle Institute (RTI), described procedures for review and approval of the teleconference minutes. Mr. Anderson suggested that members of the Committee may review electronically National Environmental Laboratory Accreditation Program (NELAP) documents (including minutes reviewed and posted by Ms. Mourrain) on the United States Environmental Protection Agency's (USEPA's) bulletin board at http://ttnwww.rtp.epa.gov or at http://134.67.104.12/html/nelac/nelac.htm#NL02.

REVIEW OF REVISIONS TO CHAPTER 6

Section 6.2 -- General Provisions

(g)

The Committee approved the addition of terminology to include renewal of NELAP accreditation.

(h)

The Committee approved the revision of this section to exclude a required time delay prior to a laboratory being free to seek accreditation from an accrediting authority other than the laboratory's home State accrediting authority.

(i)

The Committee approved this section as revised.

(j)

The Committee approved the revision of this section to require governmental laboratories with institutional conflict-of-interest issues within an accrediting authority to apply for accreditation from any other NELAP-recognized accrediting authority.

Section 6.3.3 -- Application Technical Review by a NELAP Assessment Team

(e)

The Committee approved changes in terminology in this section to indicate that a NELAP assessment team would review application documentation and accept, rather than approve, the initial application. Approvals are issued only by the NELAP Director.

(f)

The Committee approved the changes in terminology in this section that addressed a NELAP assessment team's review and acceptance of the renewal application.

6.4.1 -- Scheduling the On-Site Audits

(a)

The Committee approved the changes made for clarification of interim and renewal issues.

(b)(1)

The Committee agreed to define the logistics of the on-site audit by revising the section to read as follows: "The NELAP assessment team must send to the accrediting authority written confirmation of the logistics required to conduct the on-site audit. The written confirmation shall include, but is not limited to 1) on-site audit date, an agenda or a schedule of activities...."

Section 6.4.2 -- Conducting the On-Site Audit

(a)(3)

The Committee approved additions in this section to allow a NELAP assessment team the right to accompany an accrediting authority's assessors on an on-site audit of a laboratory.

Section 6.4.3 -- On-Site Audit Reports

(g)(3)

The Committee approved deleting the word "interim" from this section.

(h)

The Committee approved the addition to this section to clarify that only expenses for the on-site audit are addressed.

Section 6.5 -- NELAP Assessment Team Recommendations to the NELAP Director (d)

The Committee approved the revision to this section.

Section 6.6 -- Certificate of Recognition to the Accrediting Authority (b)(9)

The Committee approved the wording in this section to indicate that continued NELAP recognition is dependent upon compliance with NELAC standards to be consistent with Section 6.3.3(d)(19).

Section 6.7.1 -- NELAP Assessment Team

(b)

The Committee approved the addition of "at least one member from the USEPA" and agreed to add "at least one member from another operating state" to ensure that the NELAP assessment team would be comprised of a minimum of two individuals.

(c)

The Committee approved the addition of "at least one member from the USEPA" and agreed to add "at least one member from a NELAP-recognized accrediting authority" to ensure that the NELAP assessment team would be comprised of a minimum of two individuals. The non-USEPA team members would be from a state NELAP-recognized accrediting authority(ies).

(d)

The Committee discussed the proposed revision to this section prepared by Mr. Meyer. The Committee agreed that individuals selected for the NELAP assessment team should have an understanding of regulatory laboratory accreditation programs and current laboratory accreditation issues, but there was disagreement about establishing education/training requirements beyond those required for an accrediting authority's assessor. The Committee agreed to modify the text of Section 6.7.1(d)(3) to read as follows: "have one year of experience in administration and/or development of a regulatory laboratory accreditation program acquired within the five-year period immediately preceding appointment as a NELAP assessment team member."

Section 6.8 -- Appealing Decisions to Deny or Revoke NELAP Recognition (g)

The Committee discussed this section with respect to adding a time limitation for the NELAP Director to respond to the Appeal Board's recommendations for revocation of accreditation and suggested that this section be rewritten as follows: "The ultimate decision to grant, maintain, deny or revoke NELAP recognition remains with the NELAP Director. The Director shall notify the appealing accrediting authority of his/her decision within 15 days of receipt of recommendations from the Appeal Board." The Committee also discussed the status of NELAP recognition during the time the Appeal Board is considering a revocation of recognition and concurred that NELAP offered an accrediting authority a reasonable amount of time for compliance (modifying programs or implementing corrective actions) up to the point of an appeal. The Committee, therefore, maintained that an accrediting authority's recognition should remain revoked during the appeal process.

Section 6.9 -- Definitions

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The Committee approved the revision to this section to clarify the term "funding structure."

Section 6.2(c) -- Unconditional Reciprocity

The Committee extensively discussed the appropriateness of "unconditional" reciprocity with respect to limitations in the decision-making process of a State. Ms. Aurora Shields reported that she had discussed this issue with Dr. Charles Hartwig, Chair, NELAC Board of Directors, and indicated that Dr. Hartwig believes that states should remain autonomous and should have flexibility as NELAP-recognized accrediting authorities. Mr. Anderson reminded the Committee that the success of NELAP is critically dependent upon unconditional reciprocity. Ms. Shields interprets the term "unconditional" to mean that a State must accept everything, and, therefore, thought that the term had too many implications. Her concerns were that a reciprocal State would be required to accept all laboratory data generated by an "out-of-state" laboratory. For example, a reciprocal State could not take action to revoke the accreditation of a laboratory that was consistently providing poor data to the reciprocal State. Mr. Jack Farrell suggested that the reciprocal State could contact the home State to address the problem by asking the home State to perform an unannounced audit of the laboratory.

Ms. Shields said that Section 6.2.1(c) should be written to allow States flexibility, whereas Mr. Anderson prefers to clearly define the parameters for reciprocity so that interpretations can not differ from State to State. In this perspective, the Committee discussed parameters for reciprocity, such as application forms, results of proficiency testing (PT) study samples, and the on-site audit. The Committee concurred that, at a minimum, a laboratory should be required to provide to the reciprocating accrediting authority an application (approximately one page), the laboratory's certificate for a particular field of testing and a licensing fee. Mr. Farrell suggested that the following language be used to ensure that the application process will not be duplicated in granting reciprocity: "Each accrediting authority shall have a Policy and Procedures in place that describes how a laboratory receives reciprocity and shall not duplicate the application process for

a home State accrediting authority." Mr. Farrell suggested that the availability of the NELAP database will eliminate requirements for a laboratory to submit its certificate, because the reciprocal accrediting authority could determine the laboratory's current accreditation status electronically. However, until the database is implemented, the laboratory would need to provide its certificate to the reciprocal State.

Mr. Anderson proposed that the term "unconditional" be struck from Section 6.2(c) and that Sections 6.2(c)(3)(B) and (C) be deleted, or that Section 6.2(c)(3) be deleted in its entirety and a requirement for a provision of the laboratory's certificate be added to Section 6.2(c)(1).

(c)(4)

The Committee discussed the payment of fees to a reciprocal accrediting authority and suggested that this section be rewritten as follows: "All fees shall be paid as required by the reciprocal accrediting authority."

(c)(6)

The Committee suggested that the term "detection" be changed to "quantitation."

The issue of unconditional reciprocity was not resolved. Mr. Anderson will rewrite Section 6.2(c) as suggested by the comments from the Committee, and add this issue to the Committee's agenda for the NELAC Second Interim Meeting.

Ms. Mary Ann Feige suggested that the Committee should discuss the question of accrediting laboratories in a home State when the home State chooses to not be recognized by NELAP. At the time of NELAP implementation, the USEPA will no longer be responsible for accrediting laboratories. Although laboratories (in a home State that is not recognized by NELAP) may go out of state to seek NELAP accreditation, these laboratories also may have to seek multiple accreditations if they want to continue to do work in the home State. The question of the possibility of the USEPA maintaining a certification program in case a large number of States do not become recognized by NELAP was discussed. Mr. Anderson thought that this issue was important, but it was beyond the purview of this Committee. He suggested that Ms. Feige write a letter to the Environmental Laboratory Advisory Board (ELAB) expressing these concerns.

CONCLUSION

Mr. Anderson concluded the teleconference by indicating that the final draft of Chapter 6 would be submitted for public comment by Friday, December 20, 1996. He thanked all committee members for their willing and vigorous participation in the teleconference committee meetings held over the last couple of months.

NEXT TELECONFERENCE

The Committee suggested that another teleconference be scheduled for January 1997 to prepare for the NELAC Second Interim Meeting. Mr. Anderson will schedule a teleconference and inform the Committee.

ACTION ITEMS Accrediting Authority Committee Teleconference December 18, 1996

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Item No.	Action	Date Completed
1	Mr. Anderson will rewrite Section 6.2(c) on the basis of discussion from the Committee and add this item to the agenda of the NELAC Second Interim Meeting.	December 20, 1996
2	Mr. Anderson will rewrite Section 6.4.1(b)(1) to indicate that written confirmation to an accrediting authority from the NELAP assessment team should include an agenda and a schedule of activities for the on-site audit.	December 20, 1996
3	Mr. Anderson will add the following to Section 6.7.1(b): "at least one member from another operating state program."	December 20, 1996
4	Mr. Anderson will add the following to Section 6.7.1(c): "at least one member from a NELAP-recognized accrediting authority."	December 20, 1996
5	Mr. Anderson will rewrite Section 6.7.1(d)(3) as follows: "have one year of experience in administration and/or development of a regulatory laboratory accreditation program acquired within the five-year period immediately preceding appointment as a NELAP assessment team member."	December 20, 1996
6	Mr. Anderson will rewrite Section 6.8(g) to indicate that the NELAP Director will respond to an accrediting authority within 15 days of receipt of recommendations from the Appeal Board.	December 20, 1996

LIST OF COMMITTEE/TELECONFERENCE PARTICIPANTS Accrediting Authority Committee Teleconference December 18, 1996

Name	Affiliation	Phone/Fax/E-mail
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Ed Glick	USEPA, Cincinnati (Guest of Mary Ann Feige)	
Jack Pfaff	USEPA, Cincinnati (Guest of Mary Ann Feige)	

Jack McKenzie	Kansas Dept. of Health and Environment (Guest of Aurora Shields)	
Emily Williams (Support Contractor)	Research Triangle Institute	Tel: 919-541-6217 Fax: 919-541-5929 E-mail: emily@rti.org

AGENDA Accrediting Authority Committee Teleconference December 18, 1996

1:00 -3:00 p.m. Eastern Standard Time

Review minutes of 12/04/96

Review minutes of 12/10/96 Committee Meeting and Status of Assignments from that meeting (Minutes not yet distributed).

Discuss and hopefully approve wording changes authorized during our 12/10/96 meeting. These wording changes are shown as strike-outs and underlines in Sections 6.0 - 6.9 on pages 1-43 of Chapter 6, Revision 6, dated 12/11/96.

Discuss Jim Meyer's proposal for Sections 6.7.1 (d) and (e).

Discuss "unconditional reciprocity," Section 6.2(c).

2:45 p.m.

- Assess progress made at today's meeting.
- How to proceed from here.
- Need to submit draft of Chapter 6 for public comment by December 20, 1996.

3:00 p.m. - Automatic Shutoff.